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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,279	12/15/2004	Phillip Martin Cowley	O-2002.735 US	6683

31846 7590 08/09/2006

INTERVET INC.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,279

Applicant(s)

COWLEY ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/04</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Method claim 10 is of indeterminate scope for more than one reason. How does one determine who is in need and who is not of “inducing a agonist effect of a CB-1 receptor”? One may have no visible symptoms and still be in need. It may turn out with further research that everyone is in need. What cutoff point determines successful inducing? Specification provides no guidance. There is no art-recognized disorder known as “inducing a agonist effect of a CB-1 receptor” . Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to such a mode of action involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what “success rate” determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined “their” invention not what may be discovered by future research as this type of

claim language clearly requires.

Claims 1-5,8 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R6/R7 when not forming rings together and for the octahydro pyrido [1,2-a] pyrazine ring made, does not reasonably provide enablement for any fused piperazine permitted at R6/R7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Starting material sources for the bicyclic rings resulting from one of R6 joining with R7 are not seen but are required. Specification is silent as to the availability of necessary reactants needed to prepare such ring systems or if they are commercially available. Note In re Howarth 210 USPQ 689; Ex parte Moersch 104 USPQ 122 for the need to show starting material sources commensurate with the claims' scope. The only ring system made corresponds to ortho fusion resulting in a 6-membered ring having only carbons and the "N" attached to R7.

2.As there are no such other bicyclic compounds that have been made corresponding to the instant scope which include carbo- and heterofused rings having 4 to 7 members and having O or S, there is no reasonable basis for assuming that the myriad of compounds embraced by the all the generic claims

will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

Also note the criteria for enablement as set out in *In re Wands* cited in MPEP 2164.01(a), August 2000 edition, which includes factors such as:

- 1) Breadth of the claims- the claims cover a wide variety of fused compounds as pointed out above;
- 2) Level of unpredictability in the art- the invention is pharmaceutical in nature as it involves binding to cannabinoid receptors. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be unpredictable. See *In re Fisher* 166 USPQ 18;
- 3) Direction or guidance- as stated above the compounds made are not representative of the instant scope but are closer to each other than to remaining scope being mainly unfused at R6/R7 with one example of a fused ring system;
- 4) State of the prior art- No such fused compounds with otherwise

indolycarbonyl substitution are known in the prior art much less having the same activity as required herein;

5) Working examples- While test data has been presented only one type of fused derivative was tested as pointed out above and thus no clear evaluation of what other types of ring systems out of the many claimed might affect potency to a large or small degree.

In view of the above considerations, this rejection is being applied.

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-4, 8,10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The R6/R7 definitions appearing at the bottom of p.4 are repetitive as far as the examiner can determine.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The new fax phone

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number for the organization where this application or proceeding is assigned is
(703) 872-9306.



EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600